

REMARKS

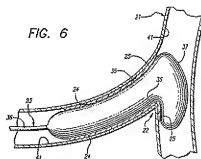
By way of summary, Claims 1–37 were pending in this application, with Claims 1–30 and 34–37 being withdrawn from consideration. Claims 31–33 were rejected in the Office Action mailed December 17, 2008, under § 103 grounds. By this Amendment, Applicant has added new Claims 38–44, cancelled withdrawn Claims 21–30, and amended Claims 31 and 32 without prejudice or disclaimer, and Applicant reserves the right to pursue the original or canceled subject matter in a continuing application. Accordingly, Claims 1–20 and 31–44 are presently pending, and Applicant respectfully requests reconsideration of this Application in view of the above-referenced amendments and following remarks.

Rejection of Claims Under 35 U.S.C. § 103

The Office Action rejected Claims 31–33 as being unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 5,607,444, to Lam, in view of U.S. Publication No. 2002/0052638, to Zadno-Azizi. Applicant respectfully submits that at least amended independent Claim 31 is patentable over the teachings of the cited references because the cited references fail to teach or suggest, alone or in combination, all the limitations of amended Claim 31, as explained further below.

Lam

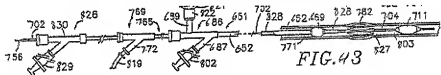
Figure 6 of Lam, reproduced here for reference, depicts a device having a balloon. Lam describes repair of a bifurcated vessel, without occluding blood flow in the vessel, that is accomplished by positioning an expandable stent within a diseased portion of the bifurcation so that a flaring portion of the stent caps the vessel ostium and a tubular body of the stent is seated within a side branch to the bifurcation. *See Abstract.*



Zadno-Azizi

Zadno-Azizi describes a catheter for use in an emboli containment system that includes a self-expanding sealing means mounted on a flexible elongate member. *See Abstract.* The reference teaches that, in order to prevent abrasion of a vessel, the self-expanding means can have a covering of a suitable material, such as a polymer, which extends over the self-expanding means (braided structure) and which moves with the braided structure as it expands and contracts. *See Abstract.*

Paragraphs [0200]-[0205] describe a device that expands two occlusion balloons 669 and 711 on opposite ends of a portion of vessel that is to be treated, as illustrated in Figure 43, reproduced here for reference. The description



provides that a stent can be expanded between the two occlusion balloons. During or after the treatment of the vessel between the two occlusion balloons, an irrigation catheter can inject a saline irrigation solution that is aspirated to clean the treatment area and remove debris therein. Para. [0200]-[0205].

Amended Independent Claim 31

Claims 31 was rejected as being unpatentable over Lam in view of Zadno-Azizi. The Office Action stated that “the claim language ‘configured to maintain the shape of the balloon in the deployed state,’ is functional language and is therefore, not given patentable weight.” Page 3. The Office Action also characterized the teachings of Lam and stated that “Zadno-Azizi teaches a balloon catheter system that uses an anchor within the balloon in paragraphs 0200-0205 for the purpose of providing additional support to the balloon.” While Applicant respectfully disagrees with the characterization of the cited references and the characterization of the

previously presented claim language, Applicant has amended Claim 31, without prejudice or disclaimer, to expedite prosecution. Applicant respectfully submits that amended Claim 31 is not rendered obvious by the cited references because the references fail to teach all the limitations of Claim 31.

For example, Claim 31 now recites, in part, “a balloon affixed to the catheter, the balloon being in fluid communication with the lumen and having contracted and deployed states, wherein the balloon comprises a predetermined shape in the deployed state; a stent having contracted and deployed states, wherein the stent is plastically deformable by the balloon and substantially conforms to the predetermined shape of the balloon in the deployed state, wherein the stent is configured to apply a compressive load on surrounding body tissue when in the deployed state; and wherein, when in the deployed state, the balloon is maintained in the predetermined shape, at least in part, by an anchor element extending along a surface of the balloon.”

Applicant respectfully submits that Lam and Zadno-Azizi fail to teach or suggest, alone or in combination, the claimed apparatus, including, at least, a balloon with a predetermined shape in a deployed state, a stent that is plastically deformable by the balloon and substantially conforms to the predetermined shape of the balloon in the deployed state, and wherein, when in the deployed state, the balloon is maintained in the predetermined shape, at least in part, by an anchor element extending along a surface of the balloon. In some embodiments, the anchor element, by extending along a surface of the balloon, limits expansion of the balloon where the anchor element is positioned or located while other portions of the balloon are free to expand. This is one way that the claimed anchor element can help maintain the balloon in the predetermined shape.

Applicant respectfully submits that the cited references fail to teach or suggest, alone or in combination, the recited apparatus of amended independent Claim 31. Accordingly, Applicant respectfully requests withdrawal of the § 103(a) rejection of Claim 31.

Dependent Claims 32–33

Claims 32–33 each depend from amended independent Claim 31, and Applicant respectfully submits that these dependent claims are patentable for at least the same reasons set forth above with respect to Claim 31, in addition to the patentable subject matter in each dependent claim. For example, Applicant respectfully submits that the cited references fail to teach or suggest, alone or in combination, the recited balloon, stent, and anchor element of Claim 31, wherein the anchor element is disposed within the balloon. With the anchor element disposed within the balloon, the anchor element is able to help maintain the balloon in the predetermined shape while reducing possible interference with the stent when the balloon plastically deforms the stent.

Accordingly, Applicant respectfully submits that Claims 32 and 33 are not obvious in view of the cited references, and Applicant respectfully requests withdrawal of the § 103(a) rejection of Claims 32 and 33.

New Claims 38–44

By this Amendment, new Claims 38–44 have been added. Applicant respectfully submits that no new matter has been added to the application by these new claims, and Applicant respectfully submits that these new claims are patentable over the cited references.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and have made a good faith effort to respond to the outstanding Office Action. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is cordially invited to contact Applicant's attorney, at the telephone number below, to resolve any such issues promptly.

Any remarks in support of patentability of one claim should not necessarily be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not necessarily be understood to base patentability on solely that portion; rather, patentability must rest on each claim taken as a whole. Applicant respectfully reserves the right to traverse any of the Examiner's rejections or assertions, even if not discussed herein. Applicant respectfully reserves the right to challenge later whether any of the cited references are prior art. Although changes to the claims have been made, no acquiescence or estoppel is or should be implied thereby; such amendments are made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter. Applicant reserves the right to contest later whether a proper reason exists to combine prior art references.

Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 50-1225 (PVI-5703A) and please credit any excess fees to such deposit account.

Respectfully submitted,

Date: March 17, 2009

/David L. Hauser/
David L. Hauser, Reg. No. 42,643
Edwards Lifesciences Corporation
Law Department
One Edwards Way
Irvine, California 92614
Telephone: (949) 250-6878
Facsimile: (949) 250-6850
Customer No. 30452

ORC 457568-1.082744.0030